HOSPIRA, INC. and ORION CORPORATION,

Plaintiffs,

v.

SANDOZ INTERNATIONAL GmbH, SANDOZ INC., and SANDOZ CANADA INC.,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIVIL ACTION No. 3:09-cv-04591 (MLC/TJB)

REDACTED

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR REQUEST TO PRECLUDE SANDOZ INC.'S AND SANDOZ CANADA'S PROPOSED INVALIDITY AND NON-INFRINGEMENT CONTENTIONS

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I. INTRODUCTION

Plaintiffs Hospira, Inc. and Orion Corporation ("Plaintiffs") submit this brief to request the Court to preclude new invalidity and non-infringement contentions that were proposed by Sandoz Inc. and Sandoz Canada ("Defendants").

This litigation arises under 21 U.S.C. § 355 and is subject to the Local Patent Rules for Hatch-Waxman litigation. Pursuant to those rules and the Court's January 6, 2010 Scheduling Order, Defendant Sandoz Inc. served invalidity and non-infringement contentions on December 31, 2009. Defendants now attempt to introduce multiple sets of proposed new contentions, which differ in character and scope from the December 31, 2009 contentions, and inject completely new issues into the case.

For the reasons set forth below, Defendants do not have good cause to serve new contentions. Further, their proposed contentions should be precluded because they require the construction of at least two additional claim terms, which will significantly delay resolution of the claim construction issues and unduly prejudice Plaintiffs. Accordingly, Plaintiffs respectfully request that the Court preclude Defendants from serving their proposed contentions.

II. SUMMARY OF ARGUMENT

Defendants' attempt to revise their contentions is exactly the type of gamesmanship the Local Patent Rules for Hatch-Waxman litigation were designed to prevent.

The Court-ordered deadline for providing invalidity and non-infringement contentions in this case was December 31, 2009. By that time, as ANDA filers, Defendants were expected to have exercised reasonable diligence in exploring and developing any invalidity and non-infringement arguments they expected to raise in this litigation. The Local Patent Rules for Hatch-Waxman litigation place this obligation on defendants because Hatch-Waxman defendants must have duly investigated their defenses prior to filing their ANDA with a Paragraph IV

certification. Early disclosure of contentions allows the parties to focus discovery and the *Markman* procedure so that the parties may reach trial efficiently prior to the expiration of the 30-month stay, thus ensuring that all relevant issues are litigated in a transparent and fair manner, and that the Court and the parties are not put in the untenable position of dealing with time-sensitive motions for injunctive relief. Now, after almost half of the 30-month stay has elapsed, Defendants seek to introduce new contentions that they had every opportunity to raise in their December 2009 contentions, had they been reasonably diligent at that time.

Defendants assert that Sandoz Canada is a new party, and thus is entitled to submit new contentions without showing any good cause. Defendants are wrong. Sandoz Canada is not a new and independent party—its substantive position is exactly the same as Sandoz Inc. [redacted]

Sandoz Canada's differing procedural posture is the result of Defendants' own prefiling maneuvers. Notably, Defendants[redacted]

However,[redacted]

[redacted]

Defendants have no good cause to serve their proposed new contentions. As detailed below, the overwhelming majority of the references added to their invalidity contentions either were known to Defendants when they served their December 2009 contentions or should have been known if they had conducted a diligent search. [redacted] Defendants do not have good cause to add new references that could and should have been identified in accordance with the schedule set by this Court.

Additionally, Defendants' proposed invalidity contentions will prejudice Plaintiffs by significantly delaying resolution of the *Markman* process. In reliance on the December 2009 contentions, the parties narrowed the terms to be interpreted by the Court to a single term in the two patents-in-suit, engaged experts, and proceeded with discovery and *Markman* briefing. The parties completed *Markman* briefing on August 6, 2010. Then, on August 16 and 27, nearly eight months after serving their original contentions, Defendants served multiple sets of new contentions. Those proposed contentions differ in character and scope from the December 2009 contentions and inject new issues into the case. In particular, they require the construction of at least two additional claim terms based on a reference that Defendants were aware of before the parties even submitted their Joint Claim Construction Statement. Defendants had this reference in hand during the entire *Markman* process but waited until after that process was complete to make new arguments that require claim construction. Such undue delay is inexcusable, not contemplated by the Local Patent Rules, and not sufficient to demonstrate good cause.

Defendants also lack good cause for serving new non-infringement contentions. Although they purport to rely on [redacted] all of the information Defendants needed to make these new arguments was available to them [redacted] Thus, Defendants had every opportunity to develop and provide their non-infringement contentions in a timely manner.

Allowing Defendants to introduce new contentions now will unduly prejudice Plaintiffs because Defendants' contentions raise new claim construction issues after *Markman* briefing has been completed. The Local Patent Rules require parties to crystallize their theories of liability, or lack thereof, early in the case and then conduct focused claim construction, fact discovery, and expert discovery based on those theories.

Defendants' deliberate actions would force Plaintiffs to replay the three-month *Markman* procedure, including briefing and depositions, and force the Court to review and consider a second set of briefs and evidence. The resulting delayed *Markman* decision will force Plaintiffs to undertake the extra burden and expense to conduct fact discovery and submit expert reports based on alternate claim constructions. Further, it is possible that Defendants could try to use the delay in resolving claim construction to prevent the Court from concluding this case prior to the expiration of the 30-month stay. The *Markman* process thus should not be reopened to deal with a reference that Defendants had in hand during that entire process—that is precisely the type of situation the Local Patent Rules were meant to avoid.

III. DEFENDANTS DO NOT HAVE GOOD CAUSE FOR INTRODUCING NEW CONTENTIONS.

As discussed above, the Local Patent Rules require the parties to exercise reasonable diligence in exploring and developing their defenses in accordance with the schedule set forth by the Court. Under the rules, Defendants had the obligation to serve comprehensive invalidity and non-infringement defenses prior to the December 2009 deadline. [redacted] Accordingly, Defendants do not have good cause to introduce new contentions, as all of the information they now seek to add was known or should have been known months ago or is not prior art. Defendants' procrastination and unjustified delay in adding such information fails to satisfy the diligence required under the Local Patent Rules.

A. Legal Standards For Showing Good Cause.

"Pursuant to Local Patent Rule 3.7, leave to amend invalidity contentions may be granted by order of the Court upon a timely application and showing of good cause." *King Pharms., Inc. v. Sandoz, Inc.*, Civil Action No. 08-5974 (GEB/DEA), 2010 U.S. Dist. LEXIS 50163, at *10 (D.N.J. May 19, 2010) (internal quotation marks omitted). Establishing good cause to amend contentions "requires a showing of diligence." *O2 Micro Int'l, Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006). The "burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence." *Id.* at 1366; *see also CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 201 (N.D. Cal. 2009) ("The party seeking to amend its contentions bears the burden of establishing diligence.")

A party that knew or should have known information, and did not timely amend its contentions, did not act with the requisite diligence. *See O2 Micro*, 467 F.3d at 1367 (holding

that a party was not diligent when it "had reason to know" of an infringement theory and "waited almost three months . . . to serve its proposed amended contentions and two more weeks to formally move to amend"); *CBS Interactive*, 257 F.R.D. at 202 (denying motion to amend where a party was aware of "sufficient details" regarding a technology months before it sought leave to amend its contentions).

Notably, Sandoz Inc. was recently denied the ability to amend its invalidity contentions in another case in this District, when it was aware of a prior art reference when it served its original contentions but did not appreciate the materiality of the reference until months later. *King Pharms.*, 2010 U.S. Dist. LEXIS 50163, at *12-13.

In addition to the diligence that is generally required by the good cause standard, Defendants must meet the requirements of the Local Patent Rules. With respect to invalidity contentions, L. Pat. R. 3.7(b) specifies that good cause may in some circumstances be shown by "recent discovery of material prior art despite earlier diligent search." To meet that standard, Defendants must show not only that they were diligent in their searches but also that the references they want to add (a) *were recently discovered*, (b) are material, and (c) *are prior art*.

With respect to non-infringement contentions, L. Pat. R. 3.7(d) specifies that good cause may be shown in some circumstances if there was "disclosure of an asserted claim and infringement contention by a Hatch-Waxman Act plaintiff under L. Pat. R. 3.6(f) that requires response by defendant because it was *not previously presented or reasonably anticipated*." (emphasis added).

B. Defendants Cannot Circumvent The Good Cause Standard Through [redacted]

Defendants assert that Sandoz Canada is entitled to serve new contentions without showing good cause because it is a new party to the lawsuit. This argument has no merit because

the contentions served in December 2009 necessarily reflect Sandoz Canada's position. Sandoz Canada is bound by the December 2009 contentions because [redacted] Indeed, as indicated above, they have the same counsel, [redacted] Any other result would be a tactical victory of form over substance—every ANDA defendant could consider [redacted] if it desired to circumvent the Local Patent Rules.

Sandoz Canada is not a newcomer to this case. Sandoz Canada [redacted] At that time, Sandoz Canada and Sandoz Inc. [redacted] Defendants also certified that they would [redacted]

The Notice Letter and the original contentions in this case necessarily reflect the position of Sandoz Canada, [redacted] *Yamanouchi Pharm. Co., v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000). The Hatch-Waxman Act requires [redacted] 21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added). The Act also requires [redacted] 21 U.S.C. § 355(j)(2)(B)(i); *see also* 21 C.F.R. § 314.95. The Notice Letter must contain "a detailed statement of the factual and legal basis of the opinion of the *applicant* that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II) (emphasis added).

[redacted] *See Yamanouchi*, 231 F.3d at 1346.

In addition, Sandoz Canada is [redacted]

[redacted] Sandoz Canada's interest in the ANDA remains identical to that of Sandoz Inc.

Thus, the December 2009 contentions necessarily reflect the position of both Defendants.

[redacted]

C. **Defendants Do Not Have Good Cause For Serving New Invalidity Contentions For The '867 Patent.**

Under the legal standards discussed above, Defendants have not shown good cause to serve new invalidity contentions related to U.S. Patent No. 6,716,867 (the "'867 patent").

Defendants [redacted][1] None of those references meet the criteria of the rules, as many of them are not prior art, have been known by Defendants for months, or should have been known to Defendants because they are readily accessible by

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1 The alleged prior art references are Talke 1995, Filos, Aho, Talke 1997, Aantaa 2006, and the [redacted] Defendants also added citations to additional documents throughout their contentions that are not listed in the chart of prior art references. [redacted] Plaintiffs object to those documents because they are not prior art.

straightforward searching through electronic databases commonly used to search for scientific literature such as Dialog and the U.S. National Library of Medicine's "PubMed" database, http://www.ncbi.nlm.nih.gov/pubmed. All of the references are improper to add for at least the reasons discussed below.

1. Defendants Have No Good Cause To Add Talke 1995 Because It Is Not Recently Discovered And Because It Will Require Construction Of Additional Claim Terms.

Defendants have no good cause for adding Talke 1995, and adding it will unduly prejudice Plaintiffs because it will require construction of at least two additional claim terms, "loading dose" and "maintenance dose."

Talke 1995 is not "recently discovered" as required by L. Pat. R. 3.7. Notably, Defendants knew about this article on or before April 22, 2010, when the parties submitted their Joint Claim Construction Statement to the Court. (D.I. 39-1.) On that same date, Defendants proposed adding Talke 1995 to Sandoz Inc.'s First Amended Answer, Affirmative Defenses, Counterclaims to Plaintiffs' Complaint and Demand for Jury Trial. (*See* Antonian Cert., Ex. J, Email from D'Amore to Chang with attachments dated April 22, 2010, "Amended Answer.")[2]

Thus, at the same time that Defendants and their counsel were drafting a detailed discussion of this reference for their Amended Answer, they agreed with Plaintiffs that the terms "loading dose" and "maintenance dose" should be removed from their list of terms to be construed. (*Compare* Antonian Cert., Ex. K, Sandoz Inc.'s Disclosure of Proposed Terms and Claim Elements for Construction Pursuant to Patent Local Rule 4.1(a) 3 *with* Antonian Cert., Ex. L, Sandoz Inc.'s Preliminary Claim Constructions and Identification of Supporting Evidence

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2 [redacted]

Pursuant to Patent Local Rule 4.2 6-7.) Unlike the construction for "d enantiomer of medetomidine," which was agreed by the parties (*see* Amended Joint Claim Construction Statement 2, D.I. 79), Defendants chose to remove "loading dose" and "maintenance dose" from the list of terms to be construed, and thus there is no agreed construction.

At the end of August, long after claim construction briefs had been completed and more than four months after appreciating the alleged materiality of the reference, Defendants added a new argument that Talke 1995 anticipates and renders obvious the claims of the '867 patent, including claim 6, which requires a "loading dose" and a "maintenance dose."

Defendants' new anticipation argument based on Talke 1995 is a claim construction argument. Talke 1995 describes a "continuous infusion" of dexmedetomidine. [redacted] Defendants suggest that, [redacted] Defendants have had this reference since before the Joint Claim Construction Statement was submitted, and never raised this claim construction argument before, in any context. They have no good cause for doing so now, and allowing these new arguments would burden Plaintiffs and the Court with the cost and delay of undertaking a new *Markman* procedure. For that reason alone, Defendants new contentions should be rejected out of hand.

2. Defendants Have No Good Cause To Add Any Of The Other References That Should Have Been Known Previously Or Are Not Prior Art.

Defendants added a series of other references that were known or should have been known when they filed their original contentions or are not prior art. All of those references are improper to add for at least the reasons discussed below.

In advance of the deadline for providing contentions, a reasonably diligent ANDA defendant would have performed at least three tasks to prepare its contentions: (1) reviewed the articles that it cited in its own Notice Letter; (2) reviewed the prior art cited in the references that formed the basis of the Notice Letter; and (3) conducted prior art searches, including keyword searches in publicly available databases of scientific and patent literature.

Had Defendants diligently performed the above-mentioned tasks, they would have been in a position in December 2009 to cite all of the references they now seek to add for the following reasons:

1. Aantaa 2006 is cited in the Notice Letter (and it is not prior art);
2. Aho and Talke 1995 are cited in Aantaa 2006; and
3. Filos 1992 and Talke 1997 could have been found by reasonably diligent searches.

The only document added by Defendants that was produced by Plaintiffs in this case is the [redacted] In addition, this document is not publicly available and thus is not prior art.

In short, none of the references added by Defendants to the '867 patent invalidity contentions are material prior art that was recently discovered despite a prior diligent search.

In addition, Defendants have proposed new arguments regarding the validity of the '867 patent under 35 U.S.C. § 112, including new arguments that are based on previously cited references. [redacted] Defendants had the patent, which is all they needed to make § 112 arguments, when they filed their December 2009 contentions. Defendants do not have good cause to reconsider and revise those arguments now.

D. Defendants Do Not Have Good Cause For Serving New Invalidity Contentions For The '214 Patent.

Under the legal standards discussed above, Defendants also do not have good cause to serve new invalidity contentions related to U.S. Patent No. 4,910,214 (the "'214 patent"). Defendants added 11 alleged prior art references. [redacted][3] None of those references meet the criteria of the rules, as many of them are not prior art or were known or should have been known by Defendants for months prior to their inclusion in Defendants' proposed amended invalidity contentions.

As noted above, a reasonably diligent ANDA defendant would have performed at least the following tasks: (1) reviewed the articles that it cited in its own Notice Letter; (2) reviewed the prior art cited in the references that formed the basis of the Notice Letter; and (3) conducted prior art searches, including keyword searches in publicly available databases of scientific and patent literature.

Had Defendants diligently performed the above-mentioned tasks, they would have been in a position in December 2009 to cite all of the references they now seek to add for the following reasons:

1. Scheinin 1987b, Virtanen 1998, and Aantaa 2006 are cited in the Notice Letter;[4]
2. Wilffert, Dabiré 1985, and Easson are cited by the Savola 1991 reference that is included in the Notice Letter; and
3. The Savola Thesis, Dabiré 1986, and Welbourn could have been found by reasonably diligent searches.

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[3] The additional alleged prior art references are Scheinin 1987b, the Savola Thesis, Wilffert, Dabiré 1985, Welbourn, Virtanen 1988, Aantaa 2006, [redacted] Dabiré 1986, and Easson.

[4] In addition, Scheinin 1987b is not material because it is cumulative, [redacted]

Further to point 3 above, Defendants have been aware of articles relating to α_2-adrenoceptor research authored or co-authored by Dr. Savola since at least July 2009 when they cited Savola 1991 in the Notice Letter, which cites at least four additional articles co-authored by him. In addition, any reasonably diligent search for references authored or co-authored by Dr. Savola related to α_2-adrenoceptors would have uncovered additional references. In fact, the title and abstract of the Savola Thesis is included in Dialog, a standard, commonly used database of scientific publications that can be accessed from anywhere in the world. The Savola Thesis can also be located and retrieved via interlibrary loan using the OCLC library database, which indicates that it is available from six sources, including the National Library of Medicine in Maryland. Moreover, Defendants have actually had the Savola Thesis since at least April 2010 when it was produced to them. (*See* Antonian Cert., Ex. M, Letter from Stempler to Mooney, April 2, 2010.)

Additionally, Defendants ostensibly added numerous references (Wilffert, Dabiré 1985, Dabiré 1986, Welbourn, and Easson) to teach about the stereoselectivity of the α_2-adrenoceptor and the motivation to separate the enantiomers of medetomidine. [redacted] Defendants made that same argument in their original contentions by citing the Wade and Ege organic chemistry textbooks. [redacted] Defendants could have acted diligently and identified the newly cited references when they served their original contentions but did not. They should have done keyword searching and reviewed the references they had already cited in their Notice Letter but did not. If Defendants had conducted a diligent search they would have found each of these references. The purpose of the Local Patent Rules is to force parties to do this type of work up front rather than to

procrastinate, cite general textbooks, and then look for more detailed references at a later, more convenient, time.

The other documents added by Defendants are [redacted] and [redacted] which have been known to Defendants since they were produced in February 2010 and are not prior art.

In short, none of the references added by Defendants to the '214 patent invalidity contentions are material prior art that Defendants reasonably could not find in time to meet the Court-ordered deadline.

In addition, Defendants have proposed revised legal arguments regarding the validity of the '214 patent under 35 U.S.C. § 112. [redacted] Defendants had the patent, which is all they needed to make those arguments, when they filed their December 2009 contentions. Defendants do not have good cause to reconsider and revise those arguments now.

E. Defendants Do Not Have Good Cause For New Non-Infringement Contentions.

Defendants have no good cause for amending their non-infringement contentions. L. Pat. R. 3.7(d) specifies that good cause may be shown in some circumstances if there was "disclosure of an asserted claim and infringement contention by a Hatch-Waxman Act plaintiff under L. Pat. R. 3.6(f) that requires response by defendant because it was not previously presented or reasonably anticipated." Plaintiffs have not asserted any new claims or made any new infringement contentions since February 2010. Thus any purported "response" by Defendants is not proper or timely.

Defendants added a significant amount of allegedly new material to their contentions, [redacted] However, all of

the information needed to make the new arguments added by Defendants was contained in the Precedex label and thus was known to them when they filed their original contentions. In addition, [redacted] Defendants could have interviewed their own expert, Dr. David Crippen, when they submitted their original contentions, but they did not. Defendants cannot overcome their lack of diligence at this late date by adding a new defense based upon previously known information.

In addition, the new non-infringement defenses raised by Defendants are futile, as Defendants only allege that some patients will not be arousable and orientated. Plaintiffs do not concede that Defendants' argument is correct or agree with Plaintiffs' [redacted] Further, Defendants' argument does not absolve them of liability for infringement or inducement of infringement of the claims of the '867 patents. Plaintiffs will be prejudiced if Defendants are allowed to amend their non-infringement contentions in violation of the Local Patent Rules and Plaintiffs are forced to address these futile new arguments for the remainder of the case.

IV. ALLOWING NEW CONTENTIONS WILL UNDULY PREJUDICE PLAINTIFFS.

Defendants should not be allowed at this late stage, and after completion of the *Markman* briefing, to add new references that require additional claim construction and do not comport with the letter or spirit of the Local Patent Rules, which are "designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *King Pharms.*, 2010 U.S. Dist. LEXIS, at *10.

The purpose of Local Patent Rules like the ones in this District is to allow parties to understand their opponents' theories of liability during discovery in a way that is more efficient than using contention interrogatories. As the Federal Circuit has explained, "allowing the parties to discover their opponent's theories of liability [] has been difficult to achieve through

traditional discovery mechanisms such as contention interrogatories. Answers to such interrogatories are often postponed until the close of discovery . . . or are amended as a matter of course during the discovery period." *O2 Micro*, 467 F.3d at 1365 (citation omitted). Local Patent Rules "are designed to address this problem by requiring both the plaintiff and the defendant in patent cases to provide early notice of their infringement and invalidity contentions, and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery." *Id.* at 1365-66.

For those reasons, establishing good cause to amend contentions "requires a showing of diligence." *Id.* at 1366. As the Federal Circuit explained, the diligence requirement gives meaning and effect to the rules. "If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery and trial preparation." *Id.*

Here, Defendants' delay in raising new issues has led directly to their potential impact on the scheduled *Markman* procedure. In particular, Defendants should not be able to add contentions that will require the construction of additional claim terms based on Talke 1995, which Defendants had in hand before the parties filed their Joint Claim Construction Statement on April 22, 2010, and long before the parties submitted *Markman* briefing in June and August 2010. Perhaps worse still, when discussing the addition of Sandoz Canada to this suit, counsel representing Sandoz Canada told this Court in May that [redacted] (*See* Antonian Cert., Ex. N, Joint Letter to Court dated May 4, 2010).

Defendants' new contentions will require the Court to construe at least two additional claim terms, "loading dose" and "maintenance dose"—terms that Defendants agreed with

Plaintiffs did not require construction.[5] The parties' exchange of terms for construction, their Joint Claim Construction Statement, and the claim construction briefs themselves were all done based in part on, and in reliance on, Defendants' original contentions. Defendants cannot get a second chance at claim construction, which is one of the most significant milestones in this patent litigation.

Allowing Defendants to serve these contentions would effectively reset the claim construction process and require a new set of *Markman* briefing and possibly depositions. If that occurs, it is highly unlikely that claim construction issues will be resolved by the Court prior to the end of fact and expert discovery. Plaintiffs will incur the additional burden and expense of conducting fact and expert discovery using alternative claim constructions. In fact, it is possible that Defendants could try to use the delay in resolving claim construction, caused by their proposed amended contentions, to prevent the Court from holding a trial and having an opportunity to decide the issues in this case prior to the expiration of the 30-month stay. This would put Plaintiffs at risk of a premature launch of Defendants' generic product, and could force this Court into urgent injunctive action instead of the deliberate, considered approach envisioned by the Local Patent Rules for Hatch-Waxman litigation.

In sum, Defendants' proposed contentions violate the Local Patent Rules in a way that unduly prejudices Plaintiffs, and should not be allowed.

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[5] In its invalidity contentions, Sandoz Canada asserts that [redacted] Plaintiffs object to any attempt by Sandoz Canada to reopen the claim construction process.

V. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court preclude Defendants' from serving their proposed contentions.

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Dated: September 10, 2010

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